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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,994	03/13/98	CHEN J	[illegible]

HM22/1014

LAHIVE & COCKFIELD
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BOSTON MA 02109

EXAMINER	
PAK, M	

ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 10/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/041,994	Chen et al.
Examiner	**Group Art Unit**
Michael Pak	1646

☒ Responsive to communication(s) filed on *Jul 26, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) *13 and 19-41* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-12 and 14-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-41* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-18 in Paper No. 10 is acknowledged.

However, examiner inadvertently included claim 13 with group I. Claim 13 should be grouped in its own Group IX. Although the product of group I and IX are directed to nucleic acid molecules, the term "antisense" has a functional definition which has acquired a status in the art separate from a nucleic acid molecule which encodes the protein or a nucleic acid molecule which hybridizes. As can be seen from the specification on pages 17-18, the term "antisense" has the pharmacological application for gene therapy which is classified under 514/44. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention.

Priority

2. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a

parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

However, the specification of the present application fails to provide the provisional application number in the first sentence.

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 1 of this application.

Claim 1 limitation directed to "at least about 70% homologous to a nucleotide sequence of SEQ ID NO:1 or a complement thereof" is not disclosed in the provisional application no. 60/073,674.

Claims 1, 2, and 5 limitation directed to "a complement thereof" is not disclosed in the provisional application no. 60/073,674.

Claim 3 limitation directed to "1922-2341 of SEQ ID NO:1" is not disclosed in the provisional application no. 60/073,674.

Claim 4 limitation directed to "3136-3622 of SEQ ID NO:1" is not disclosed in the provisional application no. 60/073,674.

Claim 6 limitation directed to "1922-2341 and 3136-3622 of SEQ ID NO:1" is not disclosed in the provisional application no. 60/073,674.

Claim 8 limitation directed to "at least about 70% homologous to the amino acid sequence of SEQ ID NO:2" is not disclosed in the provisional application no. 60/073,674.

Claims 10-11 limitation directed to "hybridizes under stringent hybridization conditions" is not disclosed in the provisional application no. 60/073,674.

Claim 11 limitation directed to "at least 500 nucleotides in length which hybridizes under stringent hybridization conditions" is not disclosed in the provisional application no. 60/073,674.

Claim 12 limitation directed to "which specifically detects a RAC3 nucleic acid molecule relative to a nucleic acid molecule encoding a non-RAC3 protein" is not disclosed in the provisional application no. 60/073,674.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37

CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required.

Claims 3-4 and 6 are directed to the limitations "1922-2341 of SEQ ID NO:1", "3136-3622 of SEQ ID NO:1", or "1922-2341 and 3136-3622 of SEQ ID NO:1", respectively, which are not disclosed in the specification.

Information Disclosure Statement

5. The information disclosure statement filed 10 February 1999 (Paper No.6) fails in part to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the list of references labeled AE-BP do not have a date in the form 1449. The references labeled AA-AD has been initialed and considered. It has been placed in the application file, but the information referred to therein has been considered as to the merits in parts only. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3, 4, and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3, 4, and 6 recite "further comprises" but the specification does not disclose isolated nucleic acid molecule which "further comprises" additional sequence of SEQ ID NO:1 sequences. The specification does not disclose the specific species of claims 3, 4, and 6.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-8, 10-12, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4 and 6 recite the term "further comprising" which is ambiguous because it is not clear what is the metes and bounds of the term. The specification fails to teach how one of skilled in the art what is the metes and bounds of a sequence that "further comprising" additional sequences of SEQ ID NO:1.

Claims 1-2 and 5 recite "complement thereof" which is confusing because it is not clear what is the metes and bounds of the term. It is not clear whether the term is referring to the fully complementary sequence or any fragment which is a complementary sequence. Furthermore, "complement" does not mean "a molecule which is the complementary sequence of SEQ ID NO:1". In order to expedited prosecution, the examiner has interpreted the term encompassing any number of fragments which are complementary to SEQ ID NO:1.

Claims 10 and 11 recite "stringent hybridization conditions" which is a relative term rendering the claims indefinite because the metes and bounds of the limitations are not clear.

Claims 1, 3-4, 6-8, 12, 14-18 encompass nucleic acid molecule with claim limitation to percent homology or identity. The state of the art is such that one skilled in the art cannot

determine what the meaning of the term "identity" is without a precise algorithm with parameters i.e. "scoring rules" (George et al.(V), page 130, right column, top paragraph, is cited as of interest to the applicant). Thus, a specific definition of "identity" must be provided taking into considerations such variables as: complete vs partial sequence, gap distances, as well as other parameters of the algorithm. The discussion on page 22 of the specification provides multiple algorithm and parameters and the claim limitation does not limit the metes and bounds of the percent homology because it is not clear which algorithm or parameters is to be used for the percent homology.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-12 and 14-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Anzick et al. ((AA); Science, 1997).

Anzick et al. disclose an isolated nucleic acid molecule encoding AIB1 which is a coactivator of a nuclear receptor (page

965, middle column). Although AIB1 has a different name from the claimed RAC3, it is structurally identical to AIB1 protein except for the number of glutamines at the C-terminus(Figure 1). Figure 4 discloses the cell comprising the vector comprising the DNA encoding AIB1 and the method of producing the protein using the cell(page 968, footnote 16). Figures 2 and 3 disclose nucleic acid hybridization of FISH and Northern analysis, respectively, using hybridizing probes. The cDNA isolated in the vector is double stranded, thus meeting the limitation of "complement thereof". In order to expedite prosecution, the term "complement thereof" has been interpreted by the examiner to mean "a complementary sequence fragment". In order to expedite prosecution, the term "further comprising" has been interpreted by the examiner to mean "wherein the isolated nucleic acid molecule comprises".

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anzick et al ((AA); Science, 1997) in view of Li et al.((AC); PNAS, 1997) and Hardy et al.((U); J. Clin. Endocrinol. Metabol., 1996).

Teachings of Anzick et al. are discussed above. Anzick et al. do not teach the nucleic acid molecule encoding SEQ ID NO:2.

Li et al. disclose an isolated nucleic acid molecule encoding RAC3 which is a coactivator of a nuclear receptor Figure 4). Although the nucleic acid molecule was isolated from the same laboratory as the claimed inventors, the reference has additional authors. Although the nucleic acid was isolated from the same laboratory, the claimed nucleic acid encoding SEQ ID

NO:2 protein encodes different number of glutamines than the Li et al. reference RAC3. Figures 1-3 and 5 disclose the cell comprising the vector comprising the DNA encoding AIB1 and the method of producing the protein using the cell.

Hardy et al. teach that CAG codon repeat which encodes glutamines in the androgen receptor disrupts function is correlated with age of onset of prostate cancer (page 4400). Hardy et al. teach that CAG codon repeats are polymorphic in humans.

It would be obvious to one of ordinary skill in the art at the time of the invention to isolate or modify the DNA of Anzick et al. to comprise different numbers of glutamine repeats because the Li et al. and Hardy et al. teach that the glutamine polymorphism with varying numbers of glutamine repeats is common in humans. Furthermore motivation is provided by Li et al. who teach the importance of mutagenesis experiments in providing further insights into the mechanism of receptor-coactivator interaction (page 8483, second column, first paragraph) especially in light of interest in the glutamine rich domain by Li et al.(page 8481, second column, first paragraph) and Anzick et al.(page 965, third column, first paragraph).

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
22 September 1999